REMARKS

In response to the Office Action mailed October 27, 2009, Applicant respectfully requests the Examiner to reconsider the above-captioned Application in view of the foregoing amendments and the following remarks.

Summary of the Office Action

In the Office Action, Claims 1, 3-10, and 14-16 stand rejected. Claims 1, 3-10 and 14-16 stand rejected under 35 U.S.C. 112, second paragraph. Claims 1, 3-10, and 14-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Resonance Frequency and Removal Torque Analysis of Implants with Turned and Anodized Surface Oxides" by Sul et al. (hereinafter "Sul"). Further, Claim 16 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Sul in view of Patent No. 5,697,779 issued to Sachdeva et al. (hereinafter "Sachdeva").

Summary of the Amendment

By this paper, Applicant has amended Claims 1, 4-5, 8, 10, and 14-17 and added new Claim 18. Accordingly, Claims 1, 3-10, 14-16, and 18 are currently pending in the present Application. By this paper, Applicant responds to the Examiner's comments and rejections made in the October 27, 2009 Office Action. Applicant respectfully submits that the present Application is in condition for allowance.

Traversal of Rejection under 35 U.S.C. § 103(a)

In the Office Action, Claims 1, 3-10 and 14-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sul. Applicant respectfully traverses this rejection and submits that Claims 1, 3-10, and 14-16 are allowable over Sul. Accordingly, Applicant respectfully requests that the rejection of Claims 1, 3-10, and 14-16 be withdrawn and that these claims be allowed.

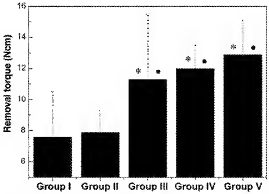
Under *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), an obviousness inquiry involves ascertaining the scope and content of the prior art, ascertaining the differences between the claimed invention and the prior art, and resolving the level of ordinary skill in the pertinent art. Applicant respectfully submits that the Office Action has improperly interpreted

the Sul reference and erroneously concluded that one of skill would have any reason to modify Sul as proposed. Instead, not only Sul fails to teach or otherwise disclose the claimed subject matter, but Sul also teaches away and provides no expectation of success to one of skill.

1. Summary of Sul

The Sul reference discusses an experimental study that was performed to investigate whether oxide properties of titanium implants influence bone tissue responses in an *in vivo* implantation.[1] *See* Sul, Abstract. The study used implant samples divided into five groups according to the anodic forming voltage used to form the titanium oxide surface layer on the implant samples. *See id.* at 254, col. 1. The titanium oxide of the implant samples of Groups I-III are characterized as being in the amorphous phase, i.e., lacking any crystallinity, while the samples of Groups IV-V seem to be characterized as having some crystalline phase (either anatase or rutile phase). *See id.* at 254, col. 2. Although Sul indicates that crystalline titanium oxide is superior to amorphous titanium oxide, Sul fails to disclose any details regarding the anatase and rutile crystalline properties of the titanium oxide of the implant samples of Groups IV-V.

At best, because Group V includes the rutile phase *in addition* to the anatase phase, Sul teaches that the removal torque of the implant samples increase as more rutile phase is used in the titanium oxide, based on Figure 2 at right. [2]



Number of implants	Group I 9	Group II 9	Group III 8	Group I 9	Group 9
Mean	7.5	7.9	11.3	12	12.9
SD	2.9	1.4	4.2	1.6	2.2
P - value (I)	.	0.999	0.023	0.006	0.001
P - value (II)	.	.	0.044	0.013	0.002

Fig. 4. Mean values of the peak removal torque measurements (Ncm) after six weeks of healing time, demonstrating statistically significant differences between Groups I and III, Groups I and IV, Groups I and V, Groups II and III, Groups II and IV, and Groups II and V. *P*-value (I) indicates the significance level in the comparisons of Groups II–V with Group I, while *P*-value (II) indicates the significance level in comparisons of Groups III–V with Group II. **P* < 0.05 in comparisons of Groups II–V with Group I • < 0.05 in comparisons of Groups III–V with Group II.

Sul is unclear regarding the specific crystalline phase used in the titanium oxide of Group IV. Initially, Sul indicates that the implants of Group IV were assigned to the anatase phase although noting that it was "a mixture of anatase and rutile phase as analysed

[1] In particular, Sul investigated "a variety of surface oxide properties, such as oxide thickness, pore configuration, crystal structure, chemical composition, and surface roughness. *See id.* at 253, col. 3.

[2] *See id.* at Fig. 3; *but see id.* at 256, col. 1 ("there were no statistically significant differences in removal torque between . . . Groups III and V and Groups IV and V.").

[sic] by Raman spectroscopy." *See id.* at 254, col. 2. Subsequently, Sul indicates that, "An anatase phase was involved in Group IV, while there were mixtures of the anatase and rutile phase in Group V." *See id.* at 257, col. 1. In contrast, Table 1 on page 255, reproduced below, indicates that the titanium oxide of Group IV was in the amorphous phase or non-crystalline form. *See id.* at 255.

Table 1. Summary of oxide growth parameters and surface characteristics of the five different types of c.p titanium implants

Oxide characteristics	Turned implants Group I	Group II	Anodised implants Group III	Group IV	Group V
Anodic forming voltage[1]	-	100 V	200 V	280 V	380 V
Oxide growth constant	-	2.03 nm/V	3.04 nm/V	2.88 nm/V	2.63 nm/V
Anodic oxide forming rate	-	16.7 nm/s	15.2 nm/s	8.9 nm/s	7.7 nm/s
Oxide thickness[2]	17 ± 6 nm	202 ± 53 nm	608 ± 127 nm	805 ± 112 nm	998 ± 199 nm
Morphology[3] ion	Turned grooves ≤ 10 μm Occasional pit and protusion	Barrier oxide film superimposed to the turned grooves≤10 μm	Porous structure	Porous structure	Porous structure
Pore size distribution[4]	-	negligable	1.27 μm² by area and ≤8 μm by length	1.53 μm² by area and ≤8 μm by length	2.10 μm² by area and ≤8 μm by length
Porosity	-	Negligible	12.70%	24.40%	18.70%
Crystallinity[5]	Amorphous titanium oxide	Amorphous titanium oxide	Amorphous phase	Amorphous phase	Anatase rutile phase
Chemical composition[6]	primarily TiO_2 and traces; C, Ca Na, Si	Primarily TiO_2 and traces: C, Ca Na, Si	Primarily TiO_2 and traces: C,Ca Na, Si	Primarily TiO_2 and traces: C, Ca Na, Si	Primarily TiO_2 and traces: C, Ca, Na, Si
Roughness (Sa)[7]	0.83 ± 0.32 μm	0.96 ± 0.34 μm	1.03 ± 0.33 μm	1.02 ± 0.27 μm	0.97 ± 0.30 μm

[1]Voltages were continuously recorded at intervals of 0.5s by an IBM computer that was interfaced with the dc power supply
[2]Measured by continuous sputter etching with 4KeV Ar ion in Auger Electron Microscopy (AES) at four different locations on each implant: one thread top, one thread valley, one thread flank and in the head of the screw implant
[3]Characterised by Scanning Electron Microscopy (SEM)
[4]Analysed by image analysis system (Bildanalyssystem AB) on negatives of the SEM pictures
[5]Measured with thin-film X-ray diffractometry (TF-XRD) and Raman spectroscopy
[6]Performed with X-ray Photoelectron Spectroscopy (XPS) with both monochromatic and non-monochromatic X-ray sources
[7]Measured with confocal laser scanning profilometer (TopScan3D®) with 245 × 245 μ?m of measuring area, in each of the three thread tops, three thread valleys and three thread flanks, with a total of 27 measurements for each group

Accordingly in light of the entire disclosure of Sul, at best, one of skill might conclude that the titanium oxide of Group IV comprised some crystalline phase titanium oxide (anatase and/or rutile), and was not 100% amorphous. Nevertheless, Sul also fails to indicate whether the titanium oxide of Group IV was 100% crystalline (whether it did not include at least some amorphous titanium oxide). More importantly, Sul is silent as to the ratios or concentration of the crystalline phases (i.e. the anatase and rutile components) of the titanium oxide of Group IV.

Further, as noted above, Sul characterizes the titanium oxide of the implant samples of Group V as "a mixture of anatase and rutile phase." *See id.* However, Sul does not indicate a ratio of the anatase phase to the rutile phase in Group V, or whether only the anatase and rutile phases were involved (or whether amorphous titanium oxide was used). Furthermore, based on Figs. 2 and 3, it would appear that the use of the rutile phase in the implants of Group V produces a superior product. Accordingly, one of skill in the art could infer that the use of the rutile phase improves the performance of the implant.

For example, as a Figure 2 clearly indicates an improved torque when the rutile phase is used. Further, while noting that the use of a crystallinity phase is superior to amorphous phase,[3] Sul also indicates that a prior study[4] performed by Li (1993) showed improved properties and testing responsiveness when using c.p. titanium and titania (rutile). *See id.* at 257, col. 2. One of skill in the art could reasonably understand Sul to teach that it is advantageous when the titanium oxide layer includes the rutile phase, and presumably, the more, the better. Accordingly, Sul teaches that crystallinity is superior to amorphousness, and that when rutile phase is used, the properties of the implant improve.

2. Sul Teaches Away From the Proposed Modification

The Office Action has asserted that it would be "obvious" to modify Sul to make the titanium oxide primarily or entirely anatase. In particular, the Office Action indicates that one of skill in the art would "make the implant of Group IV being at least 70%-100% of anatase phase in order to make experimental comparisons at least between Group IV (anatase) and Group V (mixture of anatase and rutile)." Office Action, page 3. To the contrary, Sul teaches away from increasing the proportion of the anatase phase. Thus, the modification proposed by the Office Action is improper.

Sul clearly shows that the use of the rutile phase in the oxide layer—and not just the anatase phase—produces improved results. However, Sul also seems to show that increasing the rutile phase improves these results further. For example, a comparison of Group IV (anatase only) to Group V (anatase and rutile) shows that when rutile is used, implant performance improves. *See* Sul, Fig. 2. Indeed, Figure 2 of Sul shows that removal torque increases more by using rutile phase instead of anatase phase alone. Sul also teaches that the rutile phase of Group V provides other advantages to the anatase phase of Group IV. *See id.* at 257, cols. 1-2.

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[3] Regarding the benefit of crystallinity in general, Sul indicates that the "anatase type and the anatase/rutile mixture type appear to affect bone response more than the amorphous phase does." *See id.* at 257, col. 1. Accordingly, Sul indicates that, "[a]nother oxide property that may be responsible for the improved bone responses that were seen here is the oxide crystallinity." *See id.* at 257, col. 1.

[4] Sul discusses the reports by McAlarney et al. (1996) and Li (1993) to suggest that the oxide coating is more effective with increased crystallinity. *See id.* at 257, col. 2. Sul indicates that McAlarney found that "C_3 adsorption to the anatase and rutile structure in thermal oxides increased with increasing oxide thickness and crystallinity." Then, in noting that only a few *in vivo* studies have dealt with the crystallinity of titanium oxide, Sul indicates that Li found that "bone showed a similar response to c.p. titanium and titania (rutile)." *See id.* at 257, cols. 1-2.

Additionally, one of skill in the art also appreciates that the anatase phase has different physical characteristics than the rutile phase, such as porosity, roughness, surface quality, and crystal structure. *See id.* at 257, col. 1. Due to these appreciable physical differences between the anatase phase and the rutile phase, Sul apparently teaches that the rutile phase characteristics are what improve the implant performance of Group V. Therefore, one of skill in the art would want to increase the proportion of the rutile phase—and decrease the proportion of the anatase phase—in order to improve implant performance.

Therefore, contrary to the Office Action's statement, Sul apparently teaches that 70-100% rutile phase is the target or goal, not 70-100% anatase phase. Indeed, Sul teaches away from using increasing the proportion of the anatase phase. Accordingly, Applicant respectfully submits that the rejection is improper and should be withdrawn.

3. A Person of Skill in the Art Would Have No Reason or Expectation of Success to Modify Sul as Proposed

Applicant respectfully submits that the rejection is also improper because a person of skill has no reason or expectation of success in contradicting the clear teachings of Sul.

As noted in the Office Action, Sul is silent "to the anatase phase being in a proportion of 70%-100%." *See* Office Action, page 3. Sul apparently teaches that it is better to use the rutile phase (and presumably, as much as possible) rather than use only the anatase phase. *See* Sul, at Fig. 2. Further, there is nothing in Sul (or in any reference cited by the Examiner) that would incentivize one of skill in the art to experiment by omitting the rutile phase. Thus, a person of skill has no reason to modify Sul as proposed or expectation of success in contradicting the clear teachings of Sul.

The Office Action has not provided any evidence of the level of ordinary skill in the art other than what is provided in Sul. However, the modification proposed by the Office Action contradicts what one of skill in the art is expected to do, based on the disclosure of Sul. For example, Figure 2 of Sul shows that although removal torque increases by using anatase phase (as compared to not using any crystalline phase), the removal torque increases more by using rutile phase instead of anatase phase alone. Sul also teaches that the rutile phase of Group V provides advantages to the anatase phase of Group IV. *See id.* at 257, cols. 1-2. These teachings

indicate that one of skill in the art would be expected to increase the proportion of the rutile phase in the titanium oxide.

However, the Office Action argues that it would have been obvious to one having ordinary skill in the art "to make the implant of Group IV being at least 70%-100% of anatase phase in order to make experimental comparisons at least between Group IV (anatase) and Group V (mixture of anatase and rutile)." *See* Office Action, page 3. Applicant respectfully submits that Sul teaches that such experimentation—increasing the proportion of the anatase phase in the titanium oxide—would create an inferior product.[5]

One of skill would not expect to be successful by doing the opposite of what Sul teaches. One of skill would have no reason to experiment as proposed by the Office Action. Therefore, Applicant respectfully submits that the rejection is improper and should be withdrawn.

4. The Proposed Modification is Improper Because It Would Render Sul Less Satisfactory for Its Intended Purpose

Applicant respectfully submits that the rejection is also improper because the proposed modification would render Sul's implants of Group V less satisfactory for their intended purpose. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Therefore, even one of skill in the art would not experiment as suggested by the Office Action because the modification would at best produce an implant that is inferior to the implants of Group V.

As discussed above, Sul clearly demonstrates that the implants of Group V provide superior removal torque to the implants of Group IV. If the implants of Group IV are interpreted as being in the anatase phase (as noted by Sul, albeit inconsistently), the evidence from Sul appears to demonstrate that an implant with 100% anatase would continue to have inferior properties to the implants of Group V, which use the rutile phase.

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[5] Applicant notes that Sul does not disclose proportions of the anatase phase relative to the rutile phase for either of Groups IV or V. However, the likely and logical conclusion for one of skill in the art would be to increase the use of the rutile phase and to decrease the anatase phase based on Figure 2. Indeed, contrary to the Office Action's proposition, Sul teaches that one of skill in the art would want to experiment by creating an implant with a vast majority or entirety of rutile phase crystallinity, not anatase phase crystallinity.

Therefore, based on the teachings of Sul (which represent the only pertinent evidence of record), the modification proposed by the Office Action would likely result in an implant more akin to those of Group IV, which are shown to be inferior to those of Group V. Therefore, Applicant respectfully submits that the rejection is improper because the proposed modification would render Sul's implants of Group V less satisfactory for their intended purpose.

5. Impermissible Hindsight Reasoning Was Used to Reject Claim 1 Over Sul

As discussed above, one of skill in the art would not make the inferences or mental steps proposed by the Office Action. The proposed modification of Sul is not a logical or natural mental step that would be made by one of skill in the art. Appellant notes that a judgment on obviousness can fairly use hindsight reasoning if "it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure." *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

However, as noted above, there is no evidence in the record that one of skill in the art would interpret and modify Sul as suggested by the Office Action. Further, the interpretation of the Sul and the manner in which Sul is modified seems to contravene the teachings of Sul itself. Sul simply has different teachings than that purported by the Office Action, and the Office Action's convenient modification of Sul is not a result of applying skill in the art—it is a result of impermissible hindsight reasoning.

Therefore, Appellant requests that the rejection of Claim 1, as well as Claims 6 and 9-23 be withdrawn, and that these claims be indicated as allowable over the art of record.

6. Claim 1 is Patentable Over Sul

In contrast to Sul, Claim 1 recites a dental component comprising, *inter alia*, "one or more titanium dioxide layers applied on at least one outer surface of the dental component, wherein between about 70-100% of each layer comprises crystalline titanium dioxide in the anatase phase." Applicant respectfully submits that Sul fails to teach at least the above-noted features of Claim 1. As discussed above, Sul teaches away from such a dental component and one of skill in the art has no reason or expectation of success (based on the disclosure of Sul) to

modify Sul as proposed. Further, the modification of Sul proposed by the Office Action does not render Claim 1 obvious because such a modification would make an implant that is inferior to the implant of Group V. Finally, Claim 1 is patentable because the rejection based on Sul is the product of impermissible hindsight reasoning.

Therefore, for at least these reasons, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 1, as well as the rejection of Claims 3-10 and 14-16, and indicate at that these claims are allowable over the art of record.

In re Rejection of Claim 16 under 35 U.S.C. § 103(a)

In the Office Action, Claim 16 stands rejected as being unpatentable over Sul in view of Sachdeva. Applicant respectfully traverses this rejection and submits that Claim 16 should be allowable based on its own merit and for at least the reason that Claim 16 depends from an allowable independent base claim, Claim 1. Accordingly, Applicant respectfully requests that the rejection of Claim 16 be withdrawn and that this claim be indicated as allowable over the art of record.

In re Rejection under 35 U.S.C. § 112, Second Paragraph

In the Office Action, Claims 1, 3-10 and 14-16 stand rejected under 35 U.S.C. § 112, first paragraph. Applicant has amended Claims 1, 4-5, 8, 10, and 16 to address the issued noted by the Office Action in order to expedite the prosecution of the present Application. Applicant believes that the present rejection is now moot and respectfully requests that the present rejection of Claims 1, 3-10 and 14-16 be withdrawn.

New Claim 18

Applicant hereby submits new Claim 18 for consideration. Claim 18 should be allowable based on its own merit and for at least the reason that Claim 18 depends from an allowable independent base claim, Claim 1. Accordingly, Applicant respectfully requests that Claim 16 be indicated as allowable over the art of record.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicant respectfully submits that the above rejections and objections have been overcome and that the present Application is now in condition for allowance. Therefore, Applicant respectfully requests that the Examiner indicate that Claims 1, 3-10, and 14-16 are now acceptable and allowed. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully submits that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present Application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Applicant also has not presented arguments concerning whether the applied references can be properly combined in view of, among other things, the clearly missing elements noted

above, and Applicant reserves the right to later contest whether a proper reason exists to combine these references and to submit indicia of non-obviousness.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claim and drawings in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: March 24, 2010

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